Appln. No.: 09/760,897 Attorney Docket No.: ATX-7CP4D15CNRCE

Amendment Dated: July 21, 2004

Reply to Office Action of January 21, 2004

REMARKS

I. Status of the Claims

Upon entry of the present amendment claims 83-88 and 92-97 will be pending. Claims 78-80 and 89-91 have now been cancelled, and claims 83-88 and 95 have been withdrawn. Claims 83, 85, 88, and 92-97 have been amended according to the Examiner's rejections under 35 U.S.C. § 112, second paragraph, to clarify antecedent basis and provide synonyms, neither of which affect the scope of the claims. The claims have also been amended to recite that the cells are eukaryotic cells. Support for this amendment is found throughout the Applicants' specification. Accordingly, no new matter has been added with these amendments.

II. The Objections

Claims 81 and 82 are objected to as depending on a canceled claim. Accordingly, claims 81 and 82 have been canceled without prejudice or disclaimer.

III. The Restriction Requirement and Request for Rejoinder

In the Response to Restriction Requirement dated October 9, 2003, Applicants elected Group III, claims 92-94 and 96-97 *with traverse*, and requested that Groups I-III be rejoined. In the present Office Action, the restriction was deemed final. Accordingly, in Group I claims 78-80, and in Group II claims 89-91 have been cancelled. However, with respect to claims 83-88 in Group I and claim 95 in Group II, Applicants respectfully point out that upon allowance of the

8

Appln. No.: 09/760,897

Attorney Docket No.: ATX-7CP4D15CNRCE

Amendment Dated: July 21, 2004

Reply to Office Action of January 21, 2004

product claim(s), Applicants are entitled to rejoinder of these withdrawn method claims as a matter of right pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86). See also, M.P.E.P. 821.04.

IV. The Rejections

A. Rejection Under 35 U.S.C. § 112, First Paragraph

On page 3 of the Office Action the Examiner has rejected claims 92-94, 96-97 on the grounds that they are enabled only for a eukaryotic cell. Whereas Applicants do not agree that a prokaryotic cell would not be enabled, for the sake of expediting prosecution, Applicants have amended the claim to recite that the cell is a eukaryotic cell. Applicants point out, as they have in related cases, that a prokaryotic cell could, in fact, contain unspliced eukaryotic DNA along with eukaryotic splicing enzymes so that the invention could be effected in a prokaryotic cell.

In view of the amendment, Applicants respectfully request that the grounds for rejection have been addressed and the rejection overcome. Reconsideration and withdrawal of the rejection is, therefore, respectfully requested.

B. Rejection Under 35 U.S.C. §112, Second Paragraph.

On page 4 of the Office Action claims 92-94, 96-97 have been rejected on the grounds that they are indefinite. Applicants do not believe that the claims are indefinite. Each of the

9

Appln. No.: 09/760,897 Attorney Docket No.: ATX-7CP4D15CNRCE

Amendment Dated: July 21, 2004

....

Reply to Office Action of January 21, 2004

terms would be understood by the person of ordinary skill in the art. Applicants have, nevertheless, amended the claims to provide synonyms where requested and antecedent basis also where requested.

Accordingly, in claim 92, "genetic" has been deleted so that the only antecedent is the "genetically engineered vector". In claims 92-94 and 96-97 the Examiner asserts that the phrase "being linked effectively" is not clear. Applicants believe that the person of ordinary skill in the art would have understood that this phrase refers to operable linkage. Nevertheless, Applicants have replaced this phrase with the synonymous phrase "linked operably". In claims 92-94 and 96-97 the Examiner asserts that the phrase "said cell comprising in its genome" is unclear. Applicants submit that the claimed cell literally comprises, in its genome, the claimed component. Nevertheless, Applicants have provided the synonymous phrase that the genome of the cell comprises the claimed component. Claims 92-94 and 96-97 are rejected for use of the term "upstream region". Applicants believe that the person of ordinary skill in the art would have recognized this common term of art. Nevertheless, Applicants have provided the synonymous technical term "proximal". Applicants also point out that this term is not present in claim 97.

Appln. No.: 09/760,897

Attorney Docket No.: ATX-7CP4D15CNRCE

Amendment Dated: July 21, 2004

Reply to Office Action of January 21, 2004

In view of the amendment, Applicants submit that the grounds of rejection have been addressed and the rejection overcome. Reconsideration and withdrawal of the rejection is, therefore, respectfully requested.

Applicants believe that the claims are now in condition for allowance. Early notification in that regard is requested. If the Examiner believes that a telephonic interview would expedite prosecution of this case, he is invited to contact Applicants' attorney, Anne Brown at (216) 426-3586 or Cynthia L. Kanik at (617) 227-7400.

The Commissioner is hereby authorized to charge any fee deficiency to Deposit Account No. 12-0080, referencing Attorney Docket No. ATX-007CP4DV15CNRCE.

Respectfully submitted,

Cynthia L. Kanik, Ph.D. Registration No. 37,320

For

Anne Brown

Registration No. 36,463

Date: July 21, 2004 Lahive & Cockfield 28 State Street, 24th Floor Boston, MA 02109 (617) 227-7400 (Phone) (617) 742-4214 (Fax)